PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

NIMENRIX (Meningococcal groups A, C, W-135 and Y conjugate) powder and solvent for solution

Contains sugar (sucrose)

Each dose of NIMRENIX contains 28 mg sucrose

Read all of this leaflet carefully before you receive NIMENRIX

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist, nurse or other health care provider.
- NIMENRIX has been prescribed for you or your child personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What NIMENRIX is and what it is used for

NIMENRIX is a vaccine which helps protect against infections caused by bacteria (germs) called "*Neisseria meningitidis*" types A, C, W-135 and Y.

"Neisseria meningitidis" types A, C, W-135 and Y bacteria can cause serious illnesses such as:

- meningitis - an infection of the tissue that lines the brain and spinal cord
- septicaemia - an infection of the blood

These infections are passed easily from person to person and can cause death if not treated.

NIMENRIX may be given to adults, adolescents, children and infants over 6 weeks of age.

NIMENRIX helps your body to produce its own protection (antibodies) against the bacteria. These antibodies help protect you against the diseases.

NIMENRIX will only protect against infections caused by the bacteria *"Neisseria meningitidis"* types A, C, W-135 and Y.

2. What you need to know before you receive NIMENRIX

NIMENRIX should not be administered to you if you are hypersensitive (allergic) to the active substances or any of the other ingredients of NIMENRIX (listed in section 6).

Warnings and precautions

Tell your doctor or health care provider before being given NIMENRIX:

- if you have an infection with a high temperature (over 38 °C). If this applies to you, the vaccination will not be given until you are feeling better. A minor infection such as a cold should not be a problem. However, talk to your health care provider first.
- if you have you have a bleeding problem or you bruise easily.

Fainting can occur (mostly in adolescents) following, or even before, any needle injection. Therefore, tell the doctor or nurse if you or your child fainted with a previous injection.

NIMENRIX may not fully protect everyone who is vaccinated. If you or your child has a weak immune system (such as due to human immunodeficiency virus (HIV) infection or medicines that affect the immune system), you may not receive the full benefit from NIMENRIX.

Other medicines and NIMENRIX

Always tell your health care provider if you are taking or have recently taken any other medicines or vaccines. (This includes all complementary or traditional medicines.)

NIMENRIX may not work as well if you are taking medicines that affect your immune system.

In infants, NIMENRIX can be given concomitantly with combined diphtheria - tetanus - acellular pertussis (DTaP) vaccines, including combination DTaP vaccines with hepatitis B, inactivated poliovirus or *Haemophilus influenzae* type b (HBV, IPV or Hib) such as DTaP-HBV-IPV/Hib vaccine, and with 10-valent pneumococcal conjugate vaccine.

From 1 year of age and above, NIMENRIX can be given concomitantly with any of the following vaccines: hepatitis A (HAV) and hepatitis B (HBV) vaccines, measles - mumps - rubella (MMR) vaccine, measles - mumps - rubella - varicella (MMRV) vaccine, 10-valent pneumococcal conjugate vaccine or unadjuvanted seasonal influenza vaccine.

In the second year of life, NIMENRIX can also be given concomitantly with combined diphtheria - tetanus - acellular pertussis (DTaP) vaccines, including combination DTaP vaccines with hepatitis B, inactivated poliovirus or *Haemophilus influenzae* type b (HBV, IPV or Hib) such as DTaP-HBV-IPV/Hib vaccine, and 13-valent pneumococcal conjugate vaccine.

In individuals 9 to 25 years of age, NIMENRIX can be given concomitantly with human papillomavirus vaccine [Types 16, 18] and a combined diphtheria (reduced antigen content), tetanus and acellular pertussis vaccine.

Whenever possible, NIMENRIX and a TT containing vaccine, such as DTaP-HBV-IPV/Hib vaccine, should be co-administered or NIMENRIX should be administered at least one month before the TT containing vaccine.

A different injection site will be used for each vaccine.

Pregnancy and breast-feeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before receiving NIMENRIX,

Driving and using machines

It is not always possible to predict to what extent NIMENRIX may interfere with your daily activities. You should ensure that you do not engage in the above activities until you are aware of the measure to which NIMRENIX affects you.

NIMENRIX contains sucrose and sodium

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before receiving NIMENRIX.

NIMENRIX contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially ‘sodium free’.

3. How NIMENRIX is given

Do not share medicines prescribed for you with any other person.

You will not be expected to give yourself NIMRENIX. It will be given to you by a person who is qualified to do so.

NIMENRIX is always injected into a muscle, usually in the upper arm or thigh.

Primary immunisation

Infants from 6 weeks to less than 6 months of age

Two injections given 2 months apart at e.g. 2 and 4 months of age (the first injection may be given from the age of 6 weeks).

Infants from 6 months of age, children, adolescents and adults

One injection.

Booster doses

Infants from 6 weeks to less than 12 months of age

One booster dose at 12 months of age, at least 2 months after the last dose of NIMENRIX.

Previously vaccinated individuals 12 months of age and older

Tell your doctor if you have received a previous injection with another meningococcal vaccine than NIMENRIX.

Your doctor will tell you if and when you need an additional dose of NIMENRIX, especially if you or your child:

- received your first dose at 6 - 14 months of age and could be at particular risk of infection caused by *Neisseria meningitidis* types W-135 and Y
- received your dose more than approximately one year ago and could be at risk of infection caused by *Neisseria meningitidis* type A
- received your first dose 12 - 23 months of age and could be at particular risk of infection caused by *Neisseria meningitidis* types A, C, W-135 and Y

Make sure you/your child finishes the complete vaccination course.

If you receive more NIMENRIX than you should

Since a health care provider will administer NIMENRIX, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If you forget to receive NIMENRIX

Since a health care provider will administer NIMENRIX, it is unlikely that the dose will be missed.

4. Possible side effects

NIMENRIX can have side effects.

Not all side effects reported for NIMENRIX are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving NIMRENIX, please consult your health care provider for advice.

Tell your doctor if you notice any of the following:

Frequent side effects

- loss of appetite
- feelings of irritability
- drowsiness
- headache
- stomach and digestion problems such as diarrhoea, vomiting and nausea
- fever
- swelling, pain, bruising (haematoma) and redness at the site where the injection is given
- tiredness (fatigue)
- rash (infants)

Less frequent side effects

- difficulty sleeping

- crying
- decreased feeling or sensitivity, especially on the skin
- dizziness
- itching
- rash
- aching muscles
- pain in the arms or legs
- general unwell feeling
- reactions where the injection is given including itching, a feeling of warmth, numbness or a hard lump

Other side effects

- fits (seizures) associated with a high temperature
- enlarged lymph nodes
- severe allergic reaction
- injection site swelling and redness; this may affect a large area of the vaccinated limb

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of NIMENRIX.

You can report any suspected adverse drug reactions associated with the use of the medicine directly to Pfizer via ZAF.AEReporting@pfizer.com

5. How to store NIMENRIX

- Store all medicines out of reach of children.
- Do not use this medicine after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.
- Store in the original package in order to protect from light.
- Store at or between 2 °C – 8 °C (in a refrigerator).
- After reconstitution, NIMENRIX should be used promptly. Although delay is not recommended, stability has been demonstrated for 8 hours at 30 °C after reconstitution. If not used within 8 hours, the vaccine should not be administered.
- Do not freeze.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What NIMENRIX contains

- The active substances are:

After reconstitution, 1 dose (0,5 mL) contains:

- *Neisseria meningitidis* group A polysaccharide[1] 5 micrograms
- *Neisseria meningitidis* group C polysaccharide[1] 5 micrograms
- *Neisseria meningitidis* group W-135 polysaccharide[1] 5 micrograms
- *Neisseria meningitidis* group Y polysaccharide[1] 5 micrograms
- [1]conjugated to tetanus toxoid carrier protein 44 micrograms

- The other ingredients are:
  - In the powder: sucrose and trometamol
  - In the solvent: sodium chloride and water for injections

What NIMENRIX looks like and contents of the pack

NIMENRIX is a powder and a solvent for solution for injection.

NIMENRIX is supplied as a white powder or cake in a single dose glass vial and a clear and colourless solvent in a pre-filled syringe.

These must be mixed together before use. The mixed vaccine will appear as a clear colourless solution.

NIMENRIX is available in packs of 1 or 10 with or without needles.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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